Remarks

Objection to the Drawings

The Office Action objects to Figures 1-5, which contain nucleotide and amino acid sequences, under 37 C.F.R. § 1.83. Section 1.83 states that "tables and sequence listings that are included in the specification are, except for applications filed under 35 U.S.C. 371, not permitted to be included in the drawings." This application was filed under 35 U.S.C. § 371. Please withdraw the objection.

Objection to the Claims

The Office Action objects to claims 1-3 because they encompass non-elected inventions. The Restriction Requirement mailed March 15, 2006 required an election of species "to which the claims shall be restricted if no generic claim is finally held to be allowable." Page 4. Should that occur, Applicants will amend the claims.

Claim 3 has been amended to correct an inadvertent grammatical error ("at" instead of "in" in part ii).

Please withdraw the objections.

Rejections Under 35 U.S.C. § 112 ¶ 2

Claims 1-11 stand rejected under 35 U.S.C. § 112 ¶ 2 as indefinite. Applicants respectfully traverse the rejection.

The Office Action asserts that claims 1-3 are "incomplete method claims." The Office Action cites no rules or legal basis for this assertion. To advance prosecution, however, claims 1-3 have been amended as the Office Action suggests. Claim 1 also is amended to recite "N-formyl peptide receptor like-1 (FRPL-1)" as suggested.

The Office Action contends that claims 4, 6, and 11 are indefinite because claims 2 and 3 do not recite "the step of contacting." Claims 4, 6, and 11 depend only from claim 1 (see the preliminary amendment filed October 1, 2004).

The Office Action contends that claim 5 is indefinite because claims 1-3 do not recite "the cell." Claim 5 has been amended to depend from claim 4, which provides antecedent basis for the recitation of the cell.

The Office Action contends that the recitation "compound" in claim 8 is indefinite because claim 3 recites "a test compound" and "a compound." Claim 8 depends only from claim 1 (see the preliminary amendment filed October 1, 2004).

The Office Action contends that claim 9 is indefinite because "[i]t is unclear at which step in the methods of claim 1-3 the displacement step is to be undertaken." First, claim 9 depends only from claim 1 (see the preliminary amendment filed October 1, 2004). To advance prosecution, claim 9 has been amended to recite that the ligand is "bound to the polypeptide before the step of contacting."

Please withdraw the rejection.

Rejection of Claims 1-11 Under 35 U.S.C. § 112 ¶ 1

Claims 1-11 stand rejected under 35 U.S.C. § 112 ¶ 1 as neither enabled nor sufficiently described. Applicants traverse both rejections.

Enablement

The Office Action asserts that neither the specification nor the art establish a connection between FPRL1 and any specific cardiovascular disease condition. In effect, the Office Action does not accept the specification's assertion of utility as true. But Applicants do not have to provide evidence sufficient to establish that the specification's asserted utility for the disclosed

protein is true "beyond a reasonable doubt." *In re Irons*, 340 F.2d 974, 978, 144 U.S.P.Q. (BNA) 351, 354 (C.C.P.A. 1965). It is the U.S. Patent and Trademark Office's burden to establish that the evidence of record, considered as a whole, leads a person of ordinary skill in the art to doubt that the asserted utility is true. M.P.E.P. § 2164.07(I)(C). The Office Action does not meet this burden.

The specification needs to make only one credible assertion of specific utility for the claimed invention to satisfy 35 U.S.C. § 101 and 35 U.S.C. § 112. *Raytheon v. Roper*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 835 (1984) ("When a properly claimed invention meets at least one stated objective, utility under 35 U.S.C. 101 is clearly shown."). The specification makes such an assertion. The specification teaches:

> The invention relates to novel disease associations of FPRL1 polypeptides and polynucleotides. The invention also relates to novel methods of screening for therapeutic agents for the treatment of hematological diseases, cardiovascular diseases, disorders of the peripheral and central nervous system, respiratory diseases like COPD, asthma, genito-urological disorders and inflammation diseases in a mammal. The invention also relates to pharmaceutical compositions for the treatment of hematological diseases, cardiovascular diseases, disorders of the peripheral and central nervous system, respiratory diseases like COPD, asthma, genito-urological disorders and inflammation diseases in a mammal comprising a FPRL1 polypeptide, a FPRL1 polynucleotide, or regulators of FPRL1 or modulators of FPRL1 activity.

Specification at page 4, lines 22-30. Unless there is reason to doubt the asserted utility, Applicants are entitled to a presumption that the asserted utility is sufficient to satisfy 35 U.S.C. § 101:

> As a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of § 101 for the entire claimed subject matter unless there is a reason for one skilled in the art to question the objective truth of the statement of utility or its scope.

In re Langer, 503 F.2d 1380, 1391 183 U.S.P.Q. (BNA) 288, 297 (C.C.P.A. 1974).

To overcome the presumption that Applicants' asserted utility is true, the U.S. Patent and Trademark Office must establish by a preponderance of the evidence that it is more likely than not that one of ordinary skill in the art would question the truth of the statement of utility. M.P.E.P. § 2107.2(III)(A). The Office Action has not provided such evidence.

Patentability of the claimed invention must be assessed "on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument." *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d (BNA) 1443, 1444 (Fed. Cir. 1992). A preponderance of the evidence exists when the evidence suggests that it is more likely than not that the assertion in question is true. *Herman v. Huddleston*, 459 U.S. 375, 390 (1983). The evidence of record includes all the teachings in the specification, including the expression profiles presented in Example 2.

The Office Action has not met its burden of establishing that a person of ordinary skill in the art would doubt that Applicants' asserted utility is true. Thus, the U.S. Patent and Trademark Office has not made a *prima facie* case that claims 1-11 lack utility or enablement.

Written Description

The specification as originally filed must convey clearly to those skilled in the art that the applicant invented the claimed subject matter. *In re Ruschig*, 379 F.2d 990, 996, 154 U.S.P.Q. 118, 123 (C.C.P.A. 1967). The Office Action asserts the specification does not describe the recited genus of polypeptides by anything other than sequence identity with SEQ ID NO:2. To advance prosecution, independent claims 1, 2, and 3 have been amended to recite the sequence identity as well as the requirement that the recited FPRL1 polypeptides have FPRL1 activity.

It is well known that a specification need not set forth an invention in *ipsis verbis* in order to satisfy the written description requirement. *In re Lukach*, 442 F.2d 967, 969, 160 U.S.P.Q. 795, 796 (C.C.P.A. 1971). Rather, the specification must be considered as a whole when

determining whether the written description requirement is met. *In re Wright*, 866 F.2d 422, 425, 9 U.S.P.Q.2d 1649, 1651 (Fed. Cir. 1989). One skilled in the art, considering Applicant's specification as a whole, would readily perceive that the invention encompasses assays using the recited polypeptides.

The specification both describes and enables claims 1-11. Please withdraw the rejections.

Rejections Under 35 U.S.C. § 102(b)

Claims 1-6 and 8-10 stand rejected under 35 U.S.C. § 102(b) as anticipated by Fiore.[1] Claims 1 and 11 stand rejected under 35 U.S.C. § 102(b) as anticipated by Seo.[2] Applicants respectfully traverse both rejections.

A reference cited under 35 U.S.C. § 102 must expressly or inherently describe each element set forth in the rejected claim. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Independent claims 1, 2, and 3 have been amended to recite an FPRL1 polypeptide which "has FPRL1 activity and is selected from the group consisting of (a) a polypeptide consisting of the amino acid sequence SEQ ID NO:2, (b) a polypeptide comprising the amino acid sequence SEQ ID NO:2, and (c) polypeptides which show at least 95%, 98%, or 99% homology to the amino acid sequence SEQ ID NO:2." This amendment is supported in the specification on page 9, lines 1-13. Neither Fiore nor Seo discloses the recited polypeptide. Moreover, each of claims 1, 2, and 3 recite methods of screening for therapeutic agents useful in the treatment of a disease selected from hematological diseases, cardiovascular diseases, disorders of the peripheral and central nervous system, respiratory diseases, COPD, asthma, genito-urological disorders and inflammation diseases. Neither Fiore nor Seo teaches involvement of FPRL1 with these diseases.

[1] Fiore *et al.*, *J. Exp. Med. 180*, 253-60, 1994.

Neither Fiore nor Seo teaches each element of the claims. Please withdraw the rejections.

Rejection Under 35 U.S.C. § 103(a)

Claim 7 stands rejected under 35 U.S.C. § 103(a) as obvious over Fiore in view of Ramakrishnan.[3] Claim 7 depends from claim 1, which is amended to recite an FPRL1 polypeptide which "has FPRL1 activity and is selected from the group consisting of (a) a polypeptide consisting of the amino acid sequence SEQ ID NO:2, (b) a polypeptide comprising the amino acid sequence SEQ ID NO:2, and (c) polypeptides which show at least 95%, 98%, or 99% homology to the amino acid sequence SEQ ID NO:2." Fiore does not teach or suggest the recited polypeptide. Thus, even if *arguendo* the ordinarily skilled artisan were to combine the teachings of Fiore and Ramakrishnan, the combination would not teach or suggest the subject matter of claim 7.

Please withdraw the rejection.

Respectfully submitted,

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[2] Seo *et al.*, *J. Immunol. 158*, 1895-901, 1997.

[3] Ramakrishnan, US 2002/0058258, filed March 14, 2001.